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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/628,158	07/28/2000	Raghunath Vitthal Chaudhari	5728	2931

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EXAMINER

OH, TAYLOR V

ART UNIT

PAPER NUMBER

1625

DATE MAILED: 11/05/2002 11

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/628,158

Applicant(s)

CHAUDHARI ET AL.

Examiner

Taylor Victor Oh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 July 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

Applicant's arguments with respect to claims 1-20 have been considered but are moot in view of the new ground(s) of rejection.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1 and 3-19 provisionally rejected under the judicially created doctrine of double patenting over claims 18-19, 21-23, and 25-36 of copending Application No. 09662,035. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows: both applications share

essentially the same catalysts, promoters, and organic acids used to prepare the final product.

However, the instant application differs from the Application No. 09662,035 in that there are slight variations in the amounts of catalysts, promoters, and organic acids to be used in the preparation of the 2-aryl propionic acid.

Even so, the specific steps of the Application No. 09662,035 do encompass the broader process claims in the instant application. Therefore, this is a provisional obviousness-type double patenting rejection.

Furthermore, there is no apparent reason why applicant would be prevented from presenting claims corresponding to those of the instant application in the other copending application. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

Specification

The disclosure is objected to because of the following informalities: a term "trifluoromethane sulphonic acid" is written on page 6, the last line .

Appropriate spelling correction is required.

Claim Rejections - 35 USC § 112

Claim 1 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a halide promoter, such as lithium chloride, sodium chloride, potassium chloride, lithium iodide, lithium bromide,

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sodium bromide, sodium iodide, potassium bromide, potassium iodide tetrabutyl ammonium chloride, tetrabutyl ammonium bromide, tetrabutyl ammonium iodide, tetrabutyl phosphonium chloride, tetrabutyl phosphonium bromide, or tetrabutyl phosphonium iodide, does not reasonably provide enablement for all the halide promoters in the field of organic chemistry. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to all the halide promoters unrelated to the current invention commensurate in scope with these claims. Therefore, an appropriate correction is required.

Because the specification, while being enabling for an organic acid, such as para toluene sulphonic acid, methane sulphonic acid or trifluoromethane sulphonic acid, does not reasonably provide enablement for all the organic acids in the field of chemistry. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to all the organic acids unrelated to the current invention commensurate in scope with these claims. Therefore, an appropriate correction is required. Furthermore, there are “foreman factors or Wands factors” regarding unpredictability because an organic acid includes any heterocyclic acid, any aromatic acid, any alicyclic acid, and a diverse scope of acyclic acids. In addition, it does not exclude any bi-functional acid such as a variety of amino acids. Moreover, as the molecular weight varies substantially, therefore, not all acids are liquid and also more than routine experimentation is involved. See In re Armbruster 185 USPQ 204 (CCPA 1985) and Angstadt et al., 190 USPQ 152 (CCPA 1990).

Because the specification, while being enabling for an organic solvent, such as acetone, methyl ethyl ketone, methyl isobutyl ketone, diethyl ketone, methyl n-propyl ketone, acetophenone, tetrahydrofuran, or dioxan, does not reasonably provide enablement for all the solvents selected from ketones or cyclic ethers in the field of chemistry. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to all the solvents unrelated to the current invention commensurate in scope with these claims. Therefore, an appropriate correction is required.

Claim 1 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Phrases, "general formula I", "general formula II", "general formula III", and "formula IV", are written.

However, they do not specify what those formulas are in the claim; they need to be described more in details; furthermore, it is mentioned that they are "as shown in the accompanying drawings." This is vague and indefinite. Therefore, an appropriate correction is required.

A phrase "conventional methods" is written. However, this is vague and indefinite. It does not specify what kinds of the conventional methods are employed in the process of removing the solvent from the desired product. Therefore, an appropriate correction is required.

Claim Rejections - 35 USC § 103

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Elango et al (U.S. 4,981,995) in view of Chaudhari et al (U.S. 6,093,847) .

Elango et al discloses a method of preparing ibuprofen by reacting 1-(4'-Isobutylphenyl)ethanol (56.0 mmol), $\text{PdCl}_2(\text{PPh}_3)_2$ (0.37 mmol), HCl (68 mmol) and benzene in an autoclave, which is flushed with N_2 and CO before the initiation of the reaction process; the mixture has been heated to 125-129 ° C. at a pressure of 800 psig with CO for 16 h. with stirring. The autoclave has been cooled to room temperature and vented out of CO, and the resultant mixture has been collected. Furthermore, the organic layer of the resultant mixture has got separated from the aqueous layer to isolate the desired product (see col. 10 , lines 10-24).

In addition, during the carbonylation reaction, water may be added in an amount of 10 to 600 % based on the weight of IBPE (1-(4'-Isobutylphenyl)ethanol) (see col. 3 , lines 24-28) and for other types of solvents, acetonitrile and methyl ethyl ketone can be used as solvent replacements for benzene ,along with cyclic ethers such as tetrahydrofuran and dioxane (see col. 4 , lines 20-27).

For catalysts for the reaction, some palladium complex with an appropriate ligand such as tetrakis(triphenylphosphine) complex may be employed; furthermore, the palladium metal can be placed on a suitable catalyst support such as alumina and silica (see col. 3 , lines 34-52). Also, the mole ratio of palladium to IBPE is in the range of from 1: 150 to 1:30,000 (see col. 3 , lines 64-67) whereas the mole ratio of phosphine to palladium is at least 2:1(see col. 3 , lines 60-63).

Concerning other additives, hydrogen and halide ions may be added. As for the source of halide ions, potassium, sodium, and lithium chlorides, bromides, and iodides can be useful (see col. 4 , lines 1-4) and for the source of hydrogen ions, p-toluenesulfonic acid, methanesulfonic acid are recommended as an alternative to inorganic acids(see col. 4 , lines 5-10) . The mole ratio of hydrogen ions or halide ions to IBPE may be in the range of from 0.15 to 5 (see col. 4 , lines 16-19) whereas the mole ratio of hydrogen ions or halide ions to palladium can be estimated from dividing the mole ratio of hydrogen ions or halide ions to IBPE by the mole ratio of palladium to IBPE: from the lowest value of 22.5 (0.15×150) to the highest one 150,000 ($5 \times 30,000$).

However, the instant invention differs from the Elango et al in that one of the halide promoters is tetrabutyl ammonium chloride , the water is in the range of 1 to 6 %(v/v) of the total mixture , and the reaction vessel is flushed with an inert gas after the reaction process.

Chaudhari et al discloses a process of preparing ibuprofen by reacting an aryl alcohol with a halide source, such as lithium chloride, or tetrabutyl ammonium chloride(see col. 2, lines 48-51), protonic acid, water (4% v/v) (see col. 4 , example 3), palladium catalyst with a phosphine ligand(see col. 1 ,lines 63-67) in the presence of solvents such as N-methyl-pyrrolidone (see col. 2 ,lines 61-65) in a stirred reactor.

With respect to the reaction vessel being flushed with an inert gas after the reaction process, Elango et al does teach that step before the initiation of the reaction process. It has been held that merely reversing the order of steps in a multi-step process is not a patentable modification absent unexpected or unobvious results. EX parte Rubin, 128 U.S.P.Q. 440 (P.O.B.A. 1959).

Elango et al does disclose the method of preparing ibuprofen by reacting 1-(4'-Isobutylphenyl)ethanol , $\text{PdCl}_2(\text{PPh}_3)_2$, HCl, lithium chloride as a halide source, and benzene in an autoclave at 125-129 ° C. at a pressure of 800 psig. Chaudhari et al discloses a process of preparing ibuprofen by reacting an aryl alcohol with tetrabutyl ammonium chloride as a halide source , protonic acid, water (4% v/v) palladium catalyst with a phosphine ligand in the presence of solvents such as N-methyl-pyrrolidone in a stirred reactor. Both are involved in the common process of preparing ibuprofen. Also, Chaudhari et al expressly indicates that there is an equivalency between tetrabutyl ammonium chloride and lithium chloride as for the halide source .

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Therefore, it would have been obvious to the skillful artisan in the art to have motivated to use the Chaudhari et al tetrabutyl ammonium chloride as an alternative for lithium chloride with an expectation of a similar success shown in the Chaudhari et al .

Any inquiry concerning this communications from the examiner should be directed to T. Victor Oh whose telephone number is (703)305-0809. The examiner can be normally reached on Monday through Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Alan Rotman, can be reached on (703) 308-4698. The fax number for the organization where this application or proceeding is assigned is (703)308-2742.

u/2/02

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